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EXAMINER
ADAMS, D

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-75 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☒ Claims 1-75 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Please note that in the response to the restriction requirement filed June 29, 1993, Applicant's attorney added claims 76-98 from the preliminary amendment filed May 24, 1993 to the previously designated restriction groups at the suggestion of Examiner Adams during a phone call on June 23, 1993. Applicant's attorney assigned claims 76-85 to Group II and claims 86-98 to Group I. Group I was drawn to an isolated peptide and Group II was drawn to nucleic acid, host and method of making. Applicant then elected the invention of group I drawn to an isolated peptide claims 1-9, 11-26, 29, 31-39, 50-52, 55, 60-62, 64-69, 74, and **76-85**. However, the added claims 76-85 ARE NOT DRAWN to an isolated peptide but rather are drawn to the nucleic acid and host cell while claims 86-98 ARE DRAWN to an isolated peptide. Because Applicant elected group I drawn to an isolated peptide, claims 76-85 are withdrawn from consideration as belonging to a non-elected group and claims 86-98 are examined with the elected claims of Group I.

Applicant's election with traverse of Group I in Paper No. 17 is acknowledged. Applicant states that Groups **I, IV, and V** are conceptually linked and that the claims of **group II** are directed toward a method of using the peptide of Group I to treat individuals with allergies to Japanese Cedar Pollen. However Group II is drawn to nucleic acid, host and method of making and Group IV is directed toward a method of using the peptide of Group I to treat individuals with allergies to Japanese Cedar Pollen. It is assumed that this exchange of groups was an oversight and that the traversal is directed to groups I, IV, and V. The traversal is on the

ground(s) that the subject matter of Groups IV (methods of treatment) and V (diagnostic) are conceptually linked to that of Group I (peptide) because they are methods for using the protein. Examiner agrees that the claims of Group IV should be examined with the claims of Group I because the method of treatment involves administering the peptide of Group I. However, even though there may be a conceptual link between the protein and its use as a diagnostic, this is not found persuasive because the use of the protein as diagnostic requires different method steps and would also require a different search. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9, 11-26, 29, 31-43, 50-56, 60-62, 64-70, 74, and 86-98 withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected inventions of Groups II, III, V, VI, and VII, the requirement having been traversed in Paper No. 17.

Applicant's election with traverse the species identified by the peptide CJI-22 of Group I in Paper No. 20 is acknowledged. The traversal is on the grounds that all the restricted species are closely related in that they are all peptides of about the same length derived from a single protein and are probably classed in the same class and/or subclass. Applicant's state that performing a search on all of the restricted species of peptides using an amino acid sequence database would be no more burdensome that searching the elected species particularly in view of the submission of the amino acid sequences on a computer readable disk. This is not found

persuasive because performing a search on all of the restricted species is more burdensome because each species must be searched individually. A database search of the entire protein sequence will not identify the individual peptides in the art. In addition, although the peptides are derived from a single protein, each peptide has a different amino acid sequence and all of the peptides would not be expected to have the same biological properties and activities. The requirement is still deemed to be proper and is therefore made FINAL.

The elected species of peptide CJI-22 was found to be free of the prior art and the other claimed species were searched. All of the species except CJI-1 were also free of the prior art. Therefore the election of species is withdrawn because a search on all of the claimed species was performed in view of the first elected species having been free of the prior art.

Claims 29, 31, 60, 86 and 93 are objected to as being dependent upon a non-elected base claim. Claims 29, 31, 60, 86 and 93 should be rewritten to include all the necessary limitations of the base claim and any intervening claims.

Claims 2-6, 8-26, 32-39, 50, 51, 55, 60-62, 64-69, 74, 87-97 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "isolated peptide or portion thereof" in claims 2-4 and 13-17 is unclear because the amino acid composition of this peptide or portions of the peptide is not defined.

The phrase "a portion of" in claims 5, 6, 8-12, 25, 26, 32-34, and 74 is unclear because the amino acid composition of the portion of the peptide is not defined.

The phrase "a portion thereof" in claims 18, 19, 23, 35-39, 74 is unclear because the amino acid composition of the portion of the peptide is not defined.

The phrase "modified peptide of modified portion of a peptide" in claims 20-22 is unclear because the amino acid composition of this fragment and the modifications are not defined in the claim.

The phrase "modified peptide or modified portion of a peptide" in claim 24 is unclear because the amino acid composition of the portion of the peptide is not defined and the modifications are not defined in the claim.

The phrase "at lease two peptides" in claim 50 is vague because the amino acid sequences of these peptides are not defined.

The phrase "sufficient percentage of the T cell epitopes" in claims 51 and 55 is unclear because the portion of the T cell epitopes are not identified.

The phrase "at least one antigenic fragment thereof" in claims 60 and 61 is unclear because the amino acid sequence of the fragment is not defined.

The phrase "antigenic fragment" in claim 62, 88-96 is unclear because the amino acid composition of the fragment is not defined.

The phrase "isolated antigenic fragment of *Cry j* I" in claim 64 is unclear because the amino acid composition of the fragment is not defined.

The phrases "modified" and "modified fragment" in claims 65 and 66, respectively, are unclear because the type of modification is not defined in the claim.

The phrase "antigenic fragment thereof that is immunologically related to *Cry j* I or fragment thereof" in claim 67 is unclear because the amino acid sequences of these fragments are not defined.

The phrase "at least one fragment thereof" in claims 68, 69 and 87 is unclear because the amino acid sequence of the fragment is not defined.

The phase "minimal immunoglobulin E stimulating activity" in claim 91 is unclear. Although p 11 of the specification defines minimal IgE stimulating activity as activity that is less than the amount of IgE production stimulated by the native *Cry j* I protein, an explanation of this kind should be included in the claim for clarity.

The phrase "fragment thereof" in claim 97 is unclear because the amino acid sequence of this fragment is not defined.

Claim 94 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The phrase "wherein said allergen from Japanese cedar pollen is *Cry j* I" in claim 94 does not further limit "wherein said allergen from Japanese cedar pollen is *Cry j* I" of claim 89.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide and enabling disclosure. The specification describes the nucleic acid sequence coding for *Cry j* I and the deduced amino acid sequence (p 7). The specification teaches the purification and cloning of *Cry j* I (p 29-45). The specification also discloses peptides of *Cry j* I that have T cell stimulating activity (p 45-47). The specification discloses binding assays of IgE to purified and recombinant *Cry j* I and histamine release analysis (p 48-52). The specification does not identify antigenic fragments that modify B cell responses. The specification does not identify particular antigenic fragments that bind IgE but do not result in mediator release. The specification also does not identify which modifications to *Cry j* I would result in the reduction of an allergic response following the administration of the modified *Cry j* I. The specification also does not identify fragments or portions of the peptides having T cell epitopes of *Cry j* I or any of the other properties listed above. In the absence of evidence to the contrary, it would require undo experimentation to test the isolated *Cry j* I fragments and portions of these fragments for the properties listed above.

The specification describes that the isolated *Cry j* I protein and peptides can be used in methods of modifying the allergic response of an individual sensitive to Japanese cedar pollen

allergen (p 15). The specification does not provide any *in vivo* or *in vitro* evidence that the *Cry j* I protein or isolated peptides are effective in treating sensitivity to Japanese cedar pollen allergen. Matsuhashi et al teach that the administration of intact cedar pollen allergen responsible for cedar pollinosis for hyposensitization had the drawbacks as the possibility of eliciting anaphylaxis and that the treatment had to be continued for a long time because small amounts of the allergen are administered repeatedly in order to avoid anaphylaxis (column 1, lines 40-45). Matsuhashi et al also teach that cedar pollen allergen is readily adsorbed on vessels such as glassware and metalware therefore rendering the administration of a prescribed amount of cedar pollen allergen very difficult (column 1, lines 47-51). In addition the administration of proteins and peptides for pharmaceutical therapy is unpredictable in the absence of *in vivo* clinical data for the following reasons: (1) the protein may be inactivated before producing an effect; (2) the protein may otherwise not reach the target area because (a) it may be adsorbed by fluids, cells or tissues where it has no effect or (b) it may not be able to cross the mucosa; (3) other functional properties such as adverse side effects may make the protein unsuitable for *in vivo* use. Therefore, due to the unpredictable nature of using cedar pollen allergens for therapeutic treatment, the specification does not provide evidence to convince one of ordinary skill in the art that the *Cry j* I protein and peptides would be effective in treating sensitivity to Japanese cedar pollen allergens.

Claims 1-9, 11-26, 29, 31-39, 40-43, 50-56 60-62, 64-70, 74, and 86-98 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 40-43, 53, 54, 56 and 70 are rejected under 35 U.S.C. § 101 because the invention as disclosed in inoperative and therefore lacks patentable utility. The specification fails to establish the utility of the claimed method of treatment using *Cry j* I protein and peptides for *in vivo* use in humans for the reasons discussed above in the 35 U.S.C. § 112, first paragraph rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 60, 69, 88, 89, 94 are rejected under 35 U.S.C. § 102(b) as being anticipated by Taniai et al.

Taniai et al disclose an isolated Japanese cedar pollen allergen, *Cry j* I, and antigenic fragments of *Cry j* I (p 329, column 1, paragraph 2, 330 column 1, first paragraph, and Tables 1 and 2). This protein and the fragments appear to be the same as the claimed *Cry j* I isolated protein and fragments.

Claims 65, 66 and 68 are rejected under 35 U.S.C. § 102(b) as being anticipated by Matsuhashi et al.

Matsuhashi et al disclose a modified Japanese cedar pollen allergen which is a fragment of Japanese cedar pollen covalently attached to a saccharide that reduces the allergic response of an individual to Japanese cedar pollen allergen (column 12, lines 13-23 and lines 43-52)

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this

section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 61, 64, 67, 86, 91, 92 are rejected under 35 U.S.C. § 103 as being unpatentable over Taniai et al in view of Roitt et al.

Taniai et al disclose an isolated Japanese cedar pollen allergen, *Cry j* I, and antigenic fragments of *Cry j* I (p 329, column 1, paragraph 2, 330 column 1, first paragraph, and Tables 1 and 2). Taniai et al do not disclose isolated *Cry j* or an antigenic fragment of *Cry j* I protein which does not bind IgE or which binds to a lesser extent that purified, native *Cry j* I protein. Taniai et al also do not teach an isolated *Cry j* or an antigenic fragment of *Cry j* I protein which does not bind IgE specific for Japanese cedar pollen allergen or which binds IgE to a lesser extent than native *Cry j* I protein. Taniai et al also do not teach isolated *Cry j* or an antigenic fragment of *Cry j* I protein which may bind IgE but does not result in mediator release from mast cells or basophils. Taniai et al do not teach an antigenic fragment of *Cry j* I protein which has minimal IgE stimulating activity. Taniai et al do not teach an isolated protein allergen that is immunologically related to *Cry j* I.

Roitt et al teach that Type I hypersensitivity is characterized by allergic reactions following contact with the allergen (p 19.2, column 1) Roitt al also teach that the symptoms associated with Type I hypersensitivity occur when the antigen reaches the sensitized mast cell and crosslinks surface bound IgE resulting in the release of mediators from the cell (p 19.2, Fig 19.3).

It would have been obvious to one of ordinary skill in the art to a isolate an antigenic fragment from the *Cry j* I protein taught by the Taniai et al which has minimal IgE stimulating activity and does not bind IgE, or which binds to a lesser extent than purified, native *Cry j* I protein, or which does not release mediators upon binding IgE because allergens which bind IgE lead to a Type I hypersensitivity response, as taught by Roitt et al. Therefore, in order to avoid to avoid a Type I hypersensitivity response upon administration of the fragment for therapeutic use, it would be obvious to choose a fragment with the above properties. It would have been obvious to isolated an protein allergen which is immunologically related to *Cry j* I because such an allergen would be expected to reduce symptoms of Japanese cedar pollen allergy to related allergens.

Claims 62, 70, and 93 are rejected under 35 U.S.C. § 103 as being unpatentable over Taniai et al in view of Terr.

The teachings of Taniai et al are set forth above. Taniai et al do not teach the administration of the *Cry j* I protein for treating sensitivity to a Japanese cedar pollen allergen.

Terr teaches that the repeated injections of an allergen in increasing dosage over a prolonged period of time is frequently employed in allergic rhinitis and allergic asthma (p 442, paragraph 2). Terr also teaches that immunotherapy has been shown to reduce symptoms of allergic rhinitis in patients with seasonal pollen allergy (p 442, paragraph 3).

It would have been obvious to one of ordinary skill in the art to administer the *Cry j* I protein taught Taniai et al in pharmaceutically acceptable carrier because such immunotherapy is common in the art as taught by Terr and would be expected to reduce symptoms of Japanese cedar pollen allergy.

Claims 90, 95, 96, and 97 are rejected under 35 U.S.C. § 103 as being unpatentable over Taniai et al in view of Roitt et al as in claims 61, 64, 67, 86, 91 and 92 above, and further in view of Schad et al.

The teachings of Taniai et al and Roitt et al are set forth above. The above cited art do not teach antigenic fragments of *Cry j* I which have a T cell epitope. Schad et al teach that the use of short peptides containing T cell epitopes for immunotherapy for allergy will allow alteration of the patient's immune response to the allergen without the complications inherent in IgE recognition (i.e. anaphylaxis) (p 221 column 2).

It would be obvious to one of ordinary skill in the art isolate an antigenic peptide from *Cry j* I which has a T cell epitope because this peptide could be used therapeutically for allergy desensitizations without the complications inherent in IgE recognition as taught by Schad et al.

Claims 13-17, 38, 43, 50 , 53, 55, and 56 are rejected under 35 U.S.C. § 103 as being unpatentable over Taniai et al in view of Roitt et al as in claims 61, 64, 67, 86, 91 and 92 above, and further in view of Schad et al as in claims 90, 95, 96 and 97 above and further in view of Colina et al.

The teachings of Taniai et al, Roitt et al, and Schad et al are set forth above. It would have been obvious to isolate and antigenic peptide from *Cry j* I which has a T cell epitope because this peptide could be used therapeutically for allergy desensitizations for the reasons discussed above. The above cited art do not teach peptides having a positivity index of at least about 100 and a mean T cell stimulation index of at least about 3.5.

Colina et al teach the identification of a T cell epitope in an antigen from *Onchocera volvulus* by measuring stimulation indexes greater than 4.0. Colina et al also teach that 3 of 5 patients (i.e 60%) produce a proliferative response (Figure 2 and p 1553 column 2, paragraph 4).

It would have been obvious to use stimulation index values of at least 3.5 and positivity index values of at least 100 to identify T cell epitopes from *Cry j* I because these values are used in the art to identify T cell epitopes as exemplified by Colina et al and because peptides containing these epitopes could be used therapeutically for allergy desensitizations for the reasons discussed above. It would also have been obvious to identify these epitopes by testing populations of individuals of at least 30 people because optimization of population size in order to perform statistical analysis on the data is within the skill of the ordinary artisan. It would have been obvious to isolate peptides with T cell stimulation indexes of at least 7.0 or to administer

at least two T cell epitopes because one of ordinary skill in the art would expect that either of these conditions would result in a more effective desensitization composition.

Claim 87 is rejected under 35 U.S.C. § 103 as being unpatentable over Taniai et al .

The teachings of Taniai et al are set forth above. Taniai et al do not teach a chemically synthesized *Cry j* I protein or fragment. It would have been obvious to one of ordinary skill in the art to chemically synthesize the *Cry j* I protein or fragment taught by Taniai et al because a chemically synthesized protein or fragment would be easier and less expensive to make and would be functionally equivalent to the purified protein or fragment from the purified protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Krsek-Staples whose telephone number is (703) 305-7556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission via the PTO Fax Center, located in Crystal Mall 1. The Fax Center number is

(703) 308-4227. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

JKS

Julie Krsek-Staples, Ph.D.
October 18, 1993

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180

15. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 11-26, 29, 31-39, 50-52, 55, 60-62, 64-69 and 74 drawn to an isolated peptide, classified in Class 530, subclass 324+.

II. Claims 10, 28, 30, 57-59 and 63, drawn to nucleic acid, host and method of making, classified in Class 435, subclass 69.1, 252.3 and Class 536, subclass 23.6.

III. Claim 27, drawn to a peptide comprising a combination of regions, classified in Class 530, subclass 324+.

IV. Claims 40-43, 53, 54, 56 and 70, drawn to a method of treating, classified in Class 514, subclass 12+.

V. Claims 44-49, 71 and 72, drawn to a method of detecting, classified in Class 436, subclass 501.

VI. Claim 73, drawn to a monoclonal antibody, classified in Class 530, subclass 388.1.

VII. Claim 75, drawn to a method of designing antigenic fragments, classified in Class 530, subclass 536.

16. The inventions are distinct, each from the other because of the following reasons:

17. The inventions of Groups I-III and VI represent separate and distinct products. They differ with respect to structure and physicochemical properties. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter.

18. The inventions of Groups II, IV, V and VII represent separate and distinct methods. They differ with respect to ingredients, method steps and final result. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter.

19. Inventions of Group II and Groups (I and III) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. 806.05(f)). In the instant case the product can be made by biochemical synthesis.

20. Inventions of Group I and Groups (IV, V and VII) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using

that product (M.P.E.P. 806.05(h)). In the instant case the protein can be used to generate antibodies.

21. The inventions of Groups IV-VII are unrelated to Group III. The combination peptide does not appear to have been contemplated in any of the specific methods or antibody claims. The structure of the combination peptide may be distinct from any of the individual peptides. This distinct structure may be folded in such a way as to preclude it from binding a T cell or an antibody. The combination peptide may further contain distinct epitopes generated by the peptide fusion, not considered in any of the single peptides. The combination peptide is therefore separate and distinct from any use considered for the single peptides.

22. The inventions of Groups IV, V and VII are unrelated to Group VI. The antibody of Group VI is not a component of any of the methods. It therefore represents product which is separate and distinct from the methods.

23. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, in addition to their recognized divergent subject matter, they represent an undue burden on the examiner and restriction for examination purposes as indicated is proper.

24. If Applicant elects either Group I or Group II the following election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention:

Peptide having an amino acid:

CJ1-1
CJ1-2
CJ1-3
CJ1-4
CJ1-7
CJ1-8
CJ1-9
CJ1-10
CJ1-11
CJ1-12
CJ1-14
CJ1-15
CJ1-16
CJ1-17
CJ1-18
CJ1-19

CJ1-20
CJ1-21
CJ1-22
CJ1-23
CJ1-24
CJ1-25
CJ1-26
CJ1-27
CJ1-28
CJ1-30
CJ1-31
CJ1-32
CJ1-33
CJ1-34
CJ1-35.

25. These sequences are distinct in view of their primary sequence, immunogenicity and T cell stimulation index.

26. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

27. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

28. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

29. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

30. If Applicant elects Group III the following election of species is required. This application contains claims directed

to the following patentably distinct species of the claimed invention:

Peptide having an amino acid:

CJ(1-1, 1-2 & 1-3)
CJ(1-1 & 1-2)
CJ(1-9 & 1-10)
CJ(1-14, 1-15, 1-16 & 1-17)
CJ(1-20, 1-21, 1-22 & 1-23)
CJ(1-20, 1-22 & 1-23)
CJ(1-22 & 1-23)
CJ(1-22, 1-23 & 1-24)
CJ(1-30, 1-31 & 1-32)
CJ(1-31 & 1-32)
CJ(1-22, 1-23, 1-16 & 1-17)
CJ(1-22, 1-23, 1-31 & 1-32)
CJ(1-16, 1-17, 1-31 & 1-32)
CJ(1-9, 1-10 & 1-16)
CJ(1-17, 1-22 & 1-23)
CJ(1-16, 1-17 & 1-20)
CJ(1-31, 1-32 & 1-20)
CJ(1-22, 1-23, 1-1, 1-2 & 1-3)
CJ(1-16, 1-17, 1-22, 1-23, 1-31 & 1-32)
CJ(1-9, 1-10, 1-16, 1-17, 1-22 & 1-23)
CJ(1-9, 1-10, 1-16, 1-17, 1-31 & 1-32)
CJ(1-9, 1-10, 1-22, 1-23, 1-31 & 1-32)
CJ(1-9, 1-10, 1-16, 1-17, 1-22, 1-23, 1-31 & 1-32)
CJ(1-1, 1-2, 1-16, 1-17, 1-22 & 1-23)

31. These sequences are distinct in view of their primary sequence, immunogenicity and T cell stimulation index.

32. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

33. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

34. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must

indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

35. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

36. A telephone election was not solicited due to the complexity of the restriction requirement.

37. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

38. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

39. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4227.

40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald E. Adams whose telephone number is (703) 308-0570. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

June 2, 1993

Donald E. Adams, Ph.D.

Y. CHRISTINA CHAN
PRIMARY EXAMINER
GROUP 180
Art Unit 1806